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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,823	05/23/2001	D. Wade Walke	LEX-0180-USA	8988

2423: 7590 05/19/2003

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EXAMINER
HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/19/2003 17

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary	Application No.	Applicant(s)	
	09/863,823	WALKE ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-4 and 6-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4, 6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Receipt of Applicant's arguments and amendment, filed on 28 February 2003 in Paper No.9, is acknowledged. Claim 5 has been cancelled, claims 1 and 2 have been amended and new claims 6-13 have been added. Thus claims 1-4, 6-13 are pending and under consideration.

Election/Restriction:

2. Applicant's confirmation of their election without traverse of the invention of Group I (claims 1 (in part) and 2-4) is acknowledged.

Applicants are thanked for pointing out that SEQ ID NO:4 was inadvertently left out from the restriction requirement. Applicants are also thanked for amending claim 1 to remove the non-elected SEQ ID NO:4.

The restriction requirement is still deemed proper and is therefore made FINAL.

3. The following previous objection is withdrawn in light of Applicants amendments filed in Paper No.9, 02/28/03:

(I) The objection to claim 1.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicant's arguments and amendment filed in Paper No.9, 10/08/02, have been fully considered but were not deemed persuasive.

Claim Rejections - 35 U.S.C. § 101/112

5a. Claims 1-4 stand rejected and new claims 6-13 are rejected under 35 U.S.C. 101, for reasons of record, set forth in the office action mailed on 09/28/02 in Paper No:7, pages 4-8, and reiterated here, because the claimed invention is not supported by

either a specific and substantial asserted utility or a well established utility. Applicants submit the following arguments regarding this rejection.

Applicants' first argument is that instant specification describes two coding single nucleotide polymorphism (SNPs), specifically, a G/C polymorphism at position 212 of SEQ ID NO:1, which can lead to a glycine or alanine residue at amino acid position 71 ofSDEQ ID NO:2, and A/C polymorphism at position 219 of SEQ ID NO:1, which can lead to a lysine or asparagines at amino acid position 73 of SEQ ID NO:73 of SEQ ID NO:2. Thus, Applicants argue that polymorphisms are the basis for diagnostic assays such a forensic analysis, which does not require the identification of a specific medical condition.

Applicants' second argument is that the instant polynucleotide can be used in a high throughput DNA chips, as specific markers for human genome and as targets for the discovery of drugs. Applicants contend that such "DNA chips" clearly have utility as evidenced by hundreds of issued patents. Applicants' also contend that the polynucleotide of SEQ ID NO:1, claimed in the instant application can be used to map the specific region of human chromosome 17, which contains this gene.

Applicants' third argument is that only 2-4% of the human genome actually encodes amino acid sequences, therefore, applicants conclude that the practical scientific value of biologically validated, expressed, spliced and polyadenylated mRNA sequences is readily apparent to those skilled in the art.

Applicants fourth argument is that this case is similar to in re Brana, in which the Federal Circuit admonished the P.T.O. for confusing "the requirement under the law for

obtaining a patent with the requirement for obtaining government approval to market a particular drug for human consumption".

Finally, applicants cite numerous issued patents, that Applicants assert, do not comply with the new Utility Guidelines.

Applicants' arguments have been fully considered but are deemed unpersuasive.

With respect to Applicants' first argument, it is known that some disease conditions are caused by single nucleotide polymorphism (SNP), which makes the identification of SNPs an important endeavor. However, Applicants must attach a significance to the polynucleotide of SEQ ID NO:1 and the encoded polypeptide, in order for a SNP of this polypeptide to be useful in diagnostic or forensic analysis. One of the key aspects of research in genetics is the association of sequence variation with heritable phenotypes. SNPs might accelerate the identification of disease genes by allowing researchers to look for associations between a disease and specific differences (SNPs) in a population. However, using the claimed nucleic acid in research for identifying the biological and pathological processes that the encoded protein is involved in does not afford the claimed nucleic acid specific, substantial and well established utility.

With respect to Applicants' second argument, no meaningful information will be obtained from tracking the level of expression of the claimed nucleotide or mapping the locus on a chromosome in which the claimed DNA is located, because there is no physiological or biological significance attached to these nucleotides or the encoded proteins. In order to obtain useful information, the first requirement is that one must

know the biological significance of the polynucleotides which are being evaluated. Without this information, the results of the transcript image are useless because one would not know if the polynucleotide expression should be increased or decreased or even what significance could be attributed to such changes in expression profiles. Applicants' assertion that "DNA chips" have utility is correct, however, instant application is not claiming "gene chips", (devices not much larger than postage stamps, that are based on a glass substrate wafer and contain many tiny cells - 400,000 is common, each holding DNA from a different human gene). The Patents listed by Applicants all describe a pioneering and efficient means of large scale production of miniaturized oligonucleotide arrays for sequencing, diagnostic and forensics analysis. Thus, the fact that the claimed nucleotides can be used in a DNA chip, does not provide the claimed sequences with specific and substantial utility, because without knowing the significance of the instant polynucleotide or the activity of the encoded protein, using the claimed polynucleotide in a gene chip would not yield any useful information.

With respect to Applicants' third argument, using the claimed nucleic acids to produce the encoded proteins does not afford the claimed nucleic acid specific, substantial and well established utility, because, Applicants do not disclose an activity for the encoded polypeptides, nor do they disclose the biological significance of said polypeptides.

With respect to Applicants' fourth argument, Applicants are correct in that the requirement for obtaining a patent is not the same as that of obtaining an FDA approval, however, the instant case is not similar to in re Brana, because, in In re Brana, 34

USPQ 1436, 1441 (Fed. Cir. 1995), compounds with specific structure and specific activity were claimed. Thus, in that case evidence of success in structurally similar compounds was relevant in determining whether one skilled in the art would believe an asserted utility; therefore, an implicit assertion of a tumor target was sufficiently specific to satisfy the threshold utility requirement. Furthermore, in re Brana, there were test results showing that several compounds within the scope of the claims exhibited significant antitumor activity against standard tumor model in vivo. However, instant Applicants do not provide an activity for the proteins encoded by the claimed polynucleotides, nor do they provide the physiological significance of these proteins, only, an assertion that the proteins of the instant application have structural similarity to eukaryotic membrane and secreted proteins, including , but not limited to neural cell adhesion molecules (NCAM), tyrosine kinase receptors and vascular endothelial growth factor (VEGF) receptors.

Finally, each Patent Application is examined on its' own merits and each Patent Application must meet the criteria set forth in the Revised Interim Utility Guidelines, for a specific and substantial credible asserted utility, or a well established utility. Since the instant application provides only a description for the claimed polynucleotides, and does not disclose a biological function, role or significance of the polypeptides encoded by the claimed polynucleotides, instant invention has no specific and substantial asserted utility, or a well established utility.

Therefore, the isolated nucleic acids encode polypeptides of as yet undetermined function or biological significance. Thus, unless Applicants demonstrate

the physiological significance or the biological role of the instant polynucleotides and the proteins they encode, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

6a. The claimed invention stands rejected under 35 U.S.C. 112, first paragraph, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 U.S.C. §112

7. The rejection of claim 2 made under 35 U.S.C. 112, second paragraph, is maintained for reasons of record, set forth in the office action mailed on 09/28/02 in Paper No:7, pages 8-9.

Claim 2 was amended to recite "..... hybridizes under **highly** stringent conditions....", which is still indefinite, because the specific conditions (salt, wash temperature) are not recited in the claim. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be "highly stringent."

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
May 18, 2003

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600